

1 IN THE UNITED STATES DISTRICT COURT

2 IN AND FOR THE DISTRICT OF DELAWARE

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4 IN RE: CYCLOBENZAPRINE : CIVIL ACTION
5 HYDROCHLORIDE :
6 EXTENDED-RELEASE CAPSULE :
PATENT LITIGATION, :
: NO. 09-MD-2118-SLR

7 ----- :
8 EURAND, INC., CEPHALON, : CIVIL ACTION
INC. and ANESTA AG, :
:

9 Plaintiffs :

10 v. :

11 MYLAN PHARMACEUTICALS INC., :
12 MYLAN INC., and BARR :
LABORATORIES, INC., :
:

13 Defendants : NO. 08-889-SLR

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16 Wilmington, Delaware
17 Monday, May 23, 2010
8:57 o'clock, a.m.

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19 BEFORE: HONORABLE SUE L. ROBINSON, U.S.D.C.J.

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24 Valerie J. Gunning
25 Official Court Reporter

1 APPEARANCES:

2 FISH & RICHARDSON P.C.

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4 DOUGLAS E. McCANN, ESQ.

5 -and-

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P R O C E E D I N G S

(Proceedings commenced in the courtroom,
beginning at 8:57 a.m.)

THE COURT: Good morning, counsel. Thank you
for making yourselves available.

What I plan to do is start off with some
questions for each party because, quite frankly, I don't
really know how this process works from a practical
standpoint because generally we don't get involved in this
aspect of it.

So let me start off by saying that the scenario
from which I have been operating is as follows. That if
plaintiffs should prevail on appeal and Mylan has been
allowed to continue its launch, the branded market cannot
ever truly recover.

On the opposite side, if defendants prevail on
appeal and Mylan has not been allowed to continue its
launch, there is a market for it to enter, but it will have
certainly lost money, and if other generics are allowed to
enter the market when it has not, it has potentially lost
market share and customers.

So certainly there are risks for both, and so I
need to get some fundamental information since my job is to

1 balance those risks.

2 So, Mr. Marsden, are you speaking for --

3 MR. MARSDEN: I will be speaking to certain
4 issues, but I think the first questions, Mr. Singer will
5 speak to.

6 THE COURT: All right. You're going to throw
7 him into the fire.

8 MR. MARSDEN: Yes. Throw him under the bus.
9 Yes.

10 THE COURT: Okay.

11 MR. SINGER: I think that's fair enough. Good
12 morning, your Honor. How are you? Nice to see you again.

13 THE COURT: Nice to see you.

14 MR. SINGER: I think you fairly stated what will
15 happen to the branded market.

16 THE COURT: Well, no, you are not saying
17 anything. I have questions.

18 MR. SINGER: Oh.

19 THE COURT: Yes. We're not arguing yet. I have
20 questions.

21 MR. SINGER: Okay.

22 THE COURT: Then you can argue.

23 So my first question is, tell me what an
24 authorized generic is as opposed to a generic who has had to
25 go through the ANDA process.

1 MR. SINGER: Okay. So an authorized generic as
2 opposed to Mylan and the defendants here is simply a measure
3 that a company like Cephalon can take to sort of mitigate
4 harm and capture as it were some of the generic sales.
5 That's really all it is. So when the market goes generic,
6 Cephalon can contract with another company, or itself,
7 depending on how things work, and put out a generic version
8 of the drug to capture essentially some of the sales. So
9 what it is is a mechanism to mitigate damages as opposed to
10 sort of change the dynamics of the market back to where it
11 was when Cephalon was in a position of having a branded
12 product.

13 So hopefully that answers your question.

14 THE COURT: That answers the first question.

15 MR. SINGER: Okay.

16 THE COURT: So plaintiffs benefit from the
17 authorized generic either by actually producing its own and
18 directly making the profits from that, or by authorizing a
19 third party and generating profits like that. All right. I
20 understand that.

21 So in this case, I don't really understand the
22 timing of what happened because it's my understanding that
23 plaintiffs in this case did launch its authorized generic to
24 counter -- well, that's what I want to know, that plaintiffs
25 did launch its authorized generic, and I don't know how that

1 timing coincided with its filing of a TRO.

2 MR. SINGER: And I will ask Mr. Marsden if he
3 has the facts if I get this right because this is the part
4 where we sort of split this up.

5 The timing of this was that plaintiffs learned
6 of -- plaintiffs got the Court's opinion at whatever,
7 4:00 o'clock on Thursday, read it, saw the Court's order,
8 analyzed it from our perspective, and began to discuss the
9 possibility of moving for temporary relief and contacting
10 Mylan. At the same time, the business side of the company
11 learned of Mylan's essential launch of the product and the
12 response of the authorized -- authorized generic.

13 Response was then launched in response to that
14 while at the same time the parties are in discussion or
15 attempting to discuss the aspect of moving for a temporary
16 restraining order.

17 I believe the timing is that plaintiffs
18 contacted Mylan to inform Mylan that plaintiffs were
19 intending to move for relief from the Court's order. Those
20 contacts were not returned. And then the parties both then
21 after that actually physically launched the product. It's
22 sort of at some level, they kind of merged, your Honor. I
23 mean, I don't know if anyone can show one way or the other
24 whether at 11:00 a.m. someone did this, and at 12:00 p.m.
25 someone did that.

1 THE COURT: But, to some extent, the business
2 branch was making decisions and other -- I mean, well, it
3 could be that there were more than one decision-maker and
4 they had different interests in this litigation.

5 MR. SINGER: I think it's very fluid is what --
6 it was happening very quickly in response to an order, you
7 know, received in the afternoon. And I have laid out of my
8 understanding of sort of the chronology of this, but it was
9 certainly always plaintiffs' intent right away from the
10 moment they got the order and analyzed it, if there was a
11 basis for relief, plaintiffs moved very promptly.

12 I mean, this wasn't something where plaintiffs,
13 you know, waited a couple days. You know, we contacted
14 defendants less than 24 hours later on an order received at
15 4:00 o'clock on Thursday. And, again, I don't know that
16 anybody is going to be able to demonstrate something
17 happened at 10:00 and then something happened at 11:00. We
18 just don't have that record in front of us today. But that
19 is my understanding of the chronology.

20 And, Mr. Marsden, did I get that right?

21 MR. MARSDEN: I think you did, and I will just
22 add that the authorized generic was a reaction to our
23 understanding that Mylan had launched. And the way it works
24 in the marketplace, your Honor, is that the generics
25 generally will flood the market with their product, and if

1 you don't immediately respond with the authorized generic,
2 your opportunity to capture some of that market is lost.
3 Hence, the need to act essentially on a hair trigger with
4 respect to that.

5 THE COURT: Okay. Now, my last question, and
6 then I have a series of questions for the defendants, and
7 then I will let you argue.

8 MR. SINGER: Okay.

9 THE COURT: Although I stated in my decision
10 what I thought might happen to the branded market, in other
11 words, that it really can never be recaptured if the
12 generics flood the market while we're waiting for the
13 Federal Circuit to review my decision, do you have facts,
14 figures?

15 If you can, for purposes of this record, just,
16 because I'm going to ask the defendant for the same kind of
17 information, can you tell me exactly what has happened in
18 the past and what a branded companies like plaintiffs can
19 expect to happen if I don't impose an injunction?

20 MR. SINGER: Well, what typically happens, and
21 there are studies to show this, and we can certainly provide
22 those to the Court, that in the scenario we have here of
23 sort of an oral medication in the general physician market
24 is that within -- depending on whose study you look at,
25 within three weeks to three months, the market will be

1 90-percent generic. So we could be back here in a month and
2 the market will be 90-percent generic and it will take some
3 other time frame to do that. And when I say 90-percent
4 generic, that's what I mean, that the prescriptions will be
5 filled with 90-percent generic product, whether it be from
6 Mylan and its position, or the authorized generic that's on
7 the market as well.

8 And in terms of recapturing the market, which I
9 think was sort of your --

10 THE COURT: Yes. What happens if I allowed
11 this, if I decided defendants had the better position after
12 all and I didn't enjoin their launch and then the Federal
13 Circuit said, once again, you got it wrong, Judge.

14 MR. SINGER: The Federal Circuit being what it
15 is.

16 So what happens is the market stays generic
17 right through the Federal Circuit decision. If the Federal
18 Circuit then says, no, that was incorrect, it should have
19 been -- it should have stayed branded all along, the market
20 has to be rebuilt from -- essentially from scratch, because
21 the infrastructure that was in place to sell a product such
22 as -- and it's a substantial infrastructure, is gone.

23 I mean, we put in our papers, your Honor,
24 already, Cephalon has had to give notice to layoff
25 individuals. That's the way it works. And so what happens

1 is if the Federal Circuit reverses, yes, the Mylan product
2 is no longer on the market and the market for a branded
3 cyclobenzaprine product has to be rebuilt from, I won't say
4 ground zero, because there's some good will remaining in the
5 market, but has to be rebuilt almost from scratch -- new,
6 new promotional, new salespeople, all that stuff that has
7 taken several years to be built in the first instance needs
8 to be rebuilt from scratch, and whether it can be built to
9 the same place is very unlikely.

10 THE COURT: And generally, has the Federal
11 Circuit granted motions to expedite? Does it have some
12 feeling for the exigencies of this particular kind of case?
13 And I don't even know what an expedited appeal means in the
14 Federal Circuit.

15 MR. SINGER: It's actually in the parties'
16 hands. That's the beauty of this. The Federal Circuit
17 certainly has a feeling for what's going on.

18 We cited, I hope it was in our papers earlier,
19 but certainly in our papers last night, the Eli Lilly case
20 about Actavis, where the Federal Circuit essentially put in
21 the same relief that your Honor did under 62(c), entering a
22 stay pending appeal where the patent was found invalid for
23 Eli Lilly's Actavis product pending appeal to prevent the
24 generic launch just so the Federal Circuit can essentially
25 make sure, which is what we think the statute really

1 provides for.

2 But it's in the parties' hands, your Honor,
3 because the way the Federal Circuit works is they will grant
4 the motion for expediting. If both parties are in favor of
5 it, there's no harm on them. They don't have, fairly
6 speaking, the docket you have, your Honor. It's a very
7 different docket. But the parties then control the speed of
8 the appeal by how fast they file their briefs.

9 And so if Cephalon files its brief within
10 30 days and Mylan responds within 30 days and the reply
11 brief is in 15, even some shorter period, where Cephalon
12 files its brief within two weeks and they respond within two
13 weeks, et cetera, the appeal is ready for argument as soon
14 as that last brief goes in.

15 And with a joint motion to expedite the
16 appeal, the argument will be heard on, if it's granted --
17 I can't make promises -- but will be heard very quickly
18 thereafter.

19 So that's did nice part about an expedited
20 appeal, is it's in the -- the people in this room, it's in
21 our hands to file as quickly as your Honor orders us to
22 file, and we will so do.

23 THE COURT: All right. Those are my preliminary
24 questions.

25 MR. SINGER: Okay. Very well.

1 THE COURT: I will hear from you momentarily.

2 And let's get someone up on the hot seat for
3 defendants.

4 Mr. Wallace?

5 MR. WALLACE: Good morning, your Honor.

6 Mr. Horwitz sends his apologies. He's with his 95-year-old
7 mother at the hospital.

8 THE COURT: Oh, all right. Well, I have been
9 there, done that, and I certainly accept those apologies and
10 wish him well.

11 I was amazed when I read the cases that you
12 provided to me on Friday that, according to some of the
13 language, the FDA considers the 180-day exclusivity period
14 to start ticking even after the grant of a partial summary
15 judgment, which, in my world, judgment hasn't even actually
16 been entered yet.

17 How does this -- I mean, I understand there are
18 two ways that the clock starts ticking, either by a
19 commercial launch or court decision, but in a case like
20 this, does the FDA blindly start the clock? How does it
21 start ticking, and are there any appeal processes and any
22 way to go to the FDA and say, listen, the judge did this, we
23 don't agree with it, but don't penalize us for the judge's
24 decision.

25 MR. WALLACE: You put your finger on a very

1 complicated question of law. The 180 days is clearly
2 triggered to start upon the marketing by the first to file.
3 There are other things that can trigger it, and as you
4 recall, there was some movement afoot several months ago by
5 our co-defendants to trigger -- there are certain defaults
6 that can occur.

7 And as you may recall, early on, way before
8 trial, Mylan was having some regulatory issues regarding its
9 ANDA, and there was a delay while additional testing
10 materials were submitted to the FDA.

11 Anchen and Barr, as your Honor may recall, were
12 urging your Honor, after there was a failure of evidence of
13 infringement by Anchen, to enter a final judgment in
14 Anchen's favor prior to your Honor's decision and judgment
15 against Mylan. And I don't purport to be able to stand up
16 here and lecture on all nuances of the triggers, but there
17 is one trigger that floats around, that if the first to
18 file cannot get approval and judicial clearance while
19 another ANDA filer is clear to market for 75 days, then
20 the first to file can, under those circumstances, lose its
21 exclusivity.

22 And that, in fact, is one of the reasons Mylan
23 wanted to start marketing, is because there is this threat,
24 and it's a very complicated question of law.

25 THE COURT: I understood that -- I was surprised

1 to see all the jockeying that goes on among the generics
2 with the FDA by those cases that you -- there are other
3 worlds out there that we're not always aware of.

4 MR. WALLACE: Yes, we're not always on the
5 same wavelength. I think your Honor correctly perceives
6 that. We're friendly competitors and aggressive
7 competitors.

8 So your Honor is quite right. What can trigger,
9 we could go on for hours talking about it, and people who
10 really understand it could go on for hours. But it's a very
11 complicated issue, and from Mylan's standpoint, we've been
12 litigating for several years. We tried the case. We got
13 the opinion of invalidity. We won it fair and square, and
14 that's why Mylan decided that in light of all those
15 circumstances, including the potential for forfeiture of the
16 exclusivity, launched its product.

17 THE COURT: Now, at this point, are all the
18 generics, with the exception of the authorized generic, are
19 all the generics in line involved in this litigation or are
20 there others out there in line over which I have not had
21 jurisdiction?

22 MR. WALLACE: The only generics I'm aware of
23 that are floating around here who have challenged the
24 patents are Mylan, Barr, Anchen and Impax.

25 As your Honor recalled, Impax settled after the

1 trial. Anchen has a judgment of noninfringement and
2 invalidity. And Barr, of course, has a judgment of
3 invalidity.

4 So as far as I know, that's the generic picture.
5 Barr, Anchen and Impax, of course, are barred pending the
6 180-day exclusivity, and I cannot speak to their regulatory
7 status. The last time I checked, they did not yet have
8 tentative approval from the FDA.

9 THE COURT: All right. Now, clearly, Mylan has
10 a lot to lose if I impose an injunction and Mylan's 180-day
11 exclusivity period is still ticking and they are sitting
12 there with their hands tied.

13 So my question to you is -- well, a couple of
14 questions in that regard.

15 It strikes me that there is certainly a loss of
16 money and potentially a loss of market share and customers.
17 Are there ways for me to protect Mylan, but yet protect the
18 integrity of the market and the process pending Federal
19 Circuit appeal in terms of, do I have the authority to
20 enjoin the other generics to at least you might lose your
21 180-day exclusivity, but at least you wouldn't be last on
22 the market.

23 Is there a bond that should be posted, and is
24 that permissible by plaintiffs, if defendants ultimately
25 prevail on appeal, that would at least give Mylan some

1 reimbursement for the loss of money? Are there ways,
2 practically speaking, to, again, preserve the integrity of
3 the market pending Federal Circuit appeal, but also protect
4 Mylan, because I do understand that Mylan has a position
5 that should be protected.

6 MR. WALLACE: I appreciate that question. And
7 just to break it up into bite-sized portions, as far as
8 enjoining the -- well, I would suggest that Barr, vis-a-vis
9 your Honor's litigation, is pretty much in the same
10 situation. They got a decision of invalidity.

11 My friend, Don Mizerk, representing Anchen, is
12 in a different position from Barr and Mylan in that there
13 was no evidence of infringement presented against his
14 client, so I've heard no suggestion from the plaintiffs that
15 they're somehow going to take an appeal from that judgment
16 of noninfringement when they had no evidence of
17 infringement.

18 So I'm aware of no precedence, and my guess is
19 my friend, Mr. Mizerk, is not going to volunteer any that
20 would permit your Honor to enjoin Anchen.

21 I appreciate your Honor's creative thinking to
22 figure out is there a way to somehow, in effect, recapture
23 or toll the 180 days, and we've scratched our head over the
24 very same thing and have not really come up with anything on
25 that.

1 The question of bond, and I have an agreement --
2 I don't know whether your Honor has gotten a copy of our
3 unredacted paper we filed last night.

4 THE COURT: I got it this morning as I was kind
5 of walking in.

6 MR. WALLACE: All right. Mr. Marsden and I have
7 agreed, with your Honor's permission, that we're not going
8 to mention numbers in open court.

9 THE COURT: All right.

10 MR. WALLACE: Because I don't want to have to
11 impose on your Honor or our colleagues to exit the place.

12 THE COURT: All right.

13 MR. WALLACE: But there is a number in our
14 affidavit attached to that paper, which is many times
15 more than the million dollar bond that has been suggested by
16 the plaintiffs.

17 If I could comment about this market
18 disruption --

19 THE COURT: Yes.

20 MR. WALLACE: -- that you and counsel for
21 Cephalon discussed, to be sure, with the launch of a generic
22 product, the brand product will lose market share, and there
23 have been lots of studies on this. And it depends on the
24 product. It depends on how many generics. But it will
25 clearly lose some market share. Whether it's 90 percent,

1 that might be a little too gloomy for them. Generally, they
2 don't lose much in terms of price because there will be
3 certain customers who are going to insist on the branding
4 product come hell or high water. There will be other
5 customers, mainly insurance providers, who will insist on
6 the generic if you want reimbursement.

7 So the branded product will be there. Since
8 they have an authorized generic, it's their factory making
9 those capsules, so the production will still be there. And
10 if, for some reason, your Honor is ultimately reversed, the
11 brand name is out there, the product is out there, the
12 factory is out there. The branding price has not eroded
13 that much, and obviously, if there were no generic
14 competition, they could recapture the market share and
15 increase the price.

16 So that's a little nuance on what has happened,
17 will happen, or might happen in the market, depending on
18 what goes on.

19 THE COURT: All right. So basically I think
20 what you might be saying is as follows. Judge, go ahead and
21 insist on expedited appeal regardless. You might not be
22 saying that, but I would be saying that. And because the
23 plaintiff probably -- the plaintiffs probably would not
24 agree to the kind of number that you have mentioned in your
25 papers, and because the branded product isn't going to go

1 away altogether, and your 180-day exclusivity is,
2 undoubtedly, going to go away, that it makes more sense
3 to allow Mylan to go forward, expedited appeal, and the
4 harms -- the irreparable injury weighs in favor of
5 defendants more so than plaintiffs.

6 MR. WALLACE: Well, certainly, we have no
7 objection to an expedited appeal, but I do want to address
8 one thing, and that is the four factor test. And they're
9 interesting questions about do we follow the Third Circuit
10 four factor test or do we look at the Federal Circuit.

11 THE COURT: And I actually thought the D.C.
12 Circuit, or the District of Columbia, the cases that you
13 gave me, was an interesting take. That you look at them
14 all, and it really does come down to irreparable harm, which
15 in many instances I've decided for me to predict the
16 likelihood of success at the beginning of a case, or
17 certainly what the Federal Circuit will do on appeal is just
18 a guessing game on my part.

19 But I understand that the Third Circuit standard
20 is different than what I was reading.

21 MR. WALLACE: Yes. Well, the interesting thing,
22 your Honor, of course, here, we're talking about likelihood
23 of success after two years of litigation, a seven-day trial,
24 and a decision of invalidity.

25 THE COURT: All right. Before you go any

1 further, Mr. Wallace, I think I'm done with my questions. I
2 have one more question, which I think you might have already
3 answered, but before we get into real argument, I think I
4 will need to go back to plaintiffs and have them argue and
5 then have you argue in response.

6 MR. WALLACE: Certainly.

7 THE COURT: So that I'm fair with my process.

8 And I guess in terms of -- I think you've
9 probably already answered that. In terms of facts and
10 figures associated with the consequences of an injunction
11 from Mylan, can you just tell me what you would foresee the
12 consequences of an injunction would be for Mylan for
13 purposes of the record.

14 MR. WALLACE: Absolutely. And I will be very
15 brief.

16 THE COURT: All right.

17 MR. WALLACE: In terms of lost future profit,
18 there is a number in the papers --

19 THE COURT: All right.

20 MR. WALLACE: -- we gave you. But it gets
21 bigger, your Honor, because we found out the affidavit or
22 declaration that I have attached to last night's paper was
23 done Friday morning, I think it was.

24 Since then, we have received from plaintiffs a
25 form of injunction. With that reversion, we've gotten at

1 least three or four versions of their proposed injunction.
2 With every version, it gets more onerous.

3 The provision that really creates havoc in terms
4 of customer relations and out-of-pocket cost, they are
5 asking your Honor to not only make Mylan stop distributing
6 product to the drugstores, but they are asking your Honor to
7 make Mylan recall the product that is out there, not just
8 until the drugstores stop selling, but to actually bring the
9 product back. That has three serious consequences.

10 Number one, very bad for customer relations.

11 Number two, if your Honor were to issue such an
12 injunction and the Federal Circuit were to reverse that,
13 then that would be that much more time lost in the
14 marketplace while Mylan would have to resupply the
15 drugstores.

16 But, number three, if that product comes back to
17 Mylan, it has been out of Mylan's hands, and it is millions
18 of dollars worth of product. If that product comes back to
19 Mylan, we can't just put it on the shelf for future sales.
20 Under good manufacturing procedures, that product is
21 destroyed. It is gone forever. That would increase the
22 number that is listed in the declaration we filed last night
23 by roughly 50 percent.

24 THE COURT: And before you sit down,
25 Mr. Wallace, and we get on with kind of a formal argument

1 part of this procedure, Mylan launched -- I take it
2 knowing -- I mean, there is always some risk associated
3 with a launch without having run the consequences of a
4 launch by opposing counsel and the Court, and yet here we
5 are today with my trying to sort out the aftermath of that.

6 I mean, should I hold Mylan accountable, to some
7 extent, for launching at risk, as I did in what I issued
8 last week?

9 MR. WALLACE: I think not, your Honor. And let
10 me explain. If this were a product that were earlier in its
11 life cycle, as you may recall from the trial testimony,
12 first year sales, it was a stub year, I think we're around
13 9 million. Then the next year, 40 million. I've forgotten
14 the exact numbers, but you heard it at trial.

15 This is a product which has now leveled off and
16 appears to be dwindling somewhat. It's around 130 to 140
17 million. So one factor Mylan has to consider is if we wait
18 two years, how much of a market will be there. If we wait
19 75 days, or whatever, will Anchen be doing things to trigger
20 loss of our exclusivity?

21 So those are things that have to be considered
22 in this particular situation. If there weren't other
23 generics out there, potentially triggering a forfeiture. If
24 the market were growing at a rapid pace, then it might be an
25 entirely different business decision. But those are the

1 factors that go into those business decisions. We have an
2 adjudication that the patent -- patents are invalid and
3 proceeded on that basis.

4 THE COURT: All right. So, once again, we have
5 business decisions colliding with a legal world.

6 All right. Let me go back and I will hear
7 argument, and I take it that the parties will keep my
8 balancing act in the forefront and mention it periodically
9 during their argument.

10 MR. SINGER: Yes, your Honor. And Mr. Marsden
11 would like a chance to speak as to some of the bond issues,
12 because I'm flying in from Minneapolis, wasn't quite
13 prepared for those.

14 I actually want to start where you ended with
15 Mr. Wallace, which is the nature of Mylan's decision here
16 and the extent to which this is something that can't be
17 undone because the exclusivity period has begun to run, and
18 we do agree, it has begun to run. And I think the sense of
19 the argument that I was getting from Mr. Wallace was that
20 they had sort of no choice but to do this at some level.
21 But this really is a self-inflicted wound.

22 And I can talk at length about the generic
23 exclusivity provisions, and I won't bore the Court with all
24 the different permutations that can result here, but the
25 clearest one that the Court should know about is found at

1 21 U.S.C. 355(j)(5)(D). And what that says is that the
2 Court's decision actually does not start running the clock
3 until the Federal Circuit affirms.

4 And the reason that is in there is there's
5 actually a long history about this, your Honor, and you'll
6 notice that some of the cases cited by Mylan predate 2003
7 and in relation to the generic exclusivity.

8 And what happened in 2003 is that Congress
9 amended the generic exclusivity provisions of the act. And
10 what had existed before 2003 was that your decision would
11 have actually started running the clock. That is the way it
12 used to work. And so generic companies were put to the
13 difficult choice. If they had approval from the FDA pre-
14 2003, they had to choose whether to launch at risk. And
15 branded companies on the other side were put in a difficult
16 situation. A decision from a Court would begin the run of
17 the exclusivity period.

18 And because of that input from the industry, it
19 said, hey, you know, you've set up this incentive for
20 generic exclusivity and it's having all sorts of unintended
21 consequences. Congress amended it. And what Congress did
22 in 2003, in the statutory provision that I provided, is said
23 that the actual clock for forfeiture based on your decision
24 does not start to run if there's an appeal until the appeal
25 is resolved.

1 So that's why this was a self-inflicted wound.
2 If Mylan had simply waited for the appeal to be resolved,
3 then there could have been a launch without any consequence,
4 essentially. Having sort of taken that step and ignored
5 sort of Congress' intent, and I'm not going to say Congress
6 required them to wait because Congress didn't, but certainly
7 the spirit of the act is that because of the drastic
8 consequences that happened when there's a generic launch,
9 Mylan should have waited.

10 With respect to sort of forfeiture from the
11 other defendants, we do intend to appeal the Anchen decision
12 not on the grounds of noninfringement, but if you recall,
13 your Honor, there was an extensive back and forth in the
14 case about whether plaintiffs should have to go forward
15 against Anchen and whether their ANDA was a live ANDA.
16 Remember that?

17 THE COURT: I do remember.

18 MR. SINGER: Yes. And we intend to appeal the
19 Court's decision based on that ground.

20 So there will be an appeal of the entire
21 judgment in this case, and given that, Mylan should have
22 waited. All they needed to do was respond -- they didn't
23 need to pick up the phone. They simply needed to respond to
24 phone calls from counsel. And that's why we don't think the
25 harm to them should be given substantial weight. And we

1 recognize the balancing act under 62(c) that you have to
2 perform with respect to the harm because, again, this was
3 self-inflicted.

4 One last point on where you ended up with
5 Mr. Wallace. It's a dwindling market. This is a market
6 that just got started. Cephalon didn't begin to sell this
7 product until 2007, and to walk into court and say that a
8 product that was just begun in 2007 from zero and here in
9 2011, I believe the figures are roughly \$170 million, from
10 nothing to \$170 million in a little over three-and-a-half
11 years is a dwindling market, we just disagree. That's just
12 not supported by any of the record at trial, and I think the
13 record the a trial would show the precise opposite.

14 So that's, I think, to me, I believe the biggest
15 issue here for you, whose harm matters more. And at a
16 fundamental level, the harm to Mylan was a self-inflicted
17 one. And this is something that could have been avoided
18 with, as I said, responding to counsel and conferring, and
19 we could have made motions to actually have this play out in
20 a much more orderly fashion before your Honor.

21 So that's, I think, really the gist of what I
22 wanted to do and respond on the generic exclusivity point.
23 And I'm happy to answer any questions on that.

24 I will just say, this is something the Federal
25 Circuit has done before, so you're not on some kind of

1 unique ground.

2 In the Lily versus Actavis case that I cited,
3 and it's 2010 Westlaw 337 4123, this is what the Federal
4 Circuit did. A patent was found invalid and a motion
5 under Rule 62(c), as was made by our clients, was made to
6 stay a judgment, and the Federal Circuit granted that based
7 on the analysis of the four factor test, which under 62(c)
8 sort of merges. As your Honor knows, from your Honor's own,
9 I think in the Union Carbide decision, your Honor did that
10 as well. So that, we think, is sort of the standard that
11 applies here.

12 And as we note, and I won't belabor this, we are
13 here technically on a motion for reconsideration. And what
14 we have in there is, has there been sort of a clear error by
15 the Court in balancing the harms to both parties in the
16 nature of the likelihood of success test under rule 62(c)
17 for the relief that plaintiffs are seeking, and we don't see
18 that that is there.

19 We have cited precedent to you in both
20 decisions, excuse me, in all our briefing as well as last
21 night, where the exact type of relief that plaintiffs are
22 seeking has been ordered. Even in the face of a loss --
23 and the paper I got from Mylan last night applied very much
24 a circular reason -- that since we have lost, any relief was
25 inappropriate, because they had had a trial and had won, and

1 they did, and though we think, with respect to your Honor,
2 that there are errors in that analysis.

3 But that's not how it works. Rule 62(c) exists
4 for a reason, and that reason is to balance the nature and
5 the closeness of the decision at the District Court with the
6 harms to the parties.

7 And here we think your Honor found that the
8 likelihood of success, albeit marginally, weighed in our
9 favor because of the issues that were identified, and we
10 think that balancing the harms clearly weighs in the
11 plaintiffs' favor for purposes of entering the stay of the
12 judgment so that an expedited appeal can be pursued.

13 So I think, you know, in a nutshell, I don't
14 need to belabor these points, but I think the major point
15 that I again would ask the Court to take in mind is, in
16 fact, the sort of self-inflicted nature of the harm to Mylan
17 and the dramatic harm to plaintiffs that will result. And
18 it's not a situation where in two years, we sort of flip the
19 switch and things come back on again. That's just not the
20 case.

21 As we noted in our papers, just within a week
22 of, or a few days of the Court's decision, employees were
23 given notice, a 30-day notice of having to leave. The
24 company -- and, again, restarting that process is an
25 enormous undertaking. To do that again, as it took three

1 years, and now we're being told this is a dwindling market.
2 To go from zero to 140, to go back and essentially do that
3 same thing all over again. And it's not quite the same
4 thing, because some of what -- that infrastructure does
5 exist, but most of it will be gone. And there's really
6 no -- there's really nothing to be done about that if the
7 Court does not issue the injunction, or the stay, excuse me,
8 of its judgment for appeal.

9 So that's, in a nutshell, the argument. I will
10 be happy to answer any questions, particularly on the
11 generic exclusivity point, because I know it's a source of a
12 lot of confusion, but I have laid out, that is the provision
13 that applies here. Had they simply waited for appeal, we
14 would not be here today.

15 THE COURT: And I guess what concerns me is not
16 so much -- well, is the maneuver by the other generics while
17 this is being stayed for Mylan, one generic. I mean, how do
18 I address all the other folks out there who were vying for
19 market position and Mylan has its hands tied, setting aside
20 the self-inflicted --

21 MR. SINGER: I will set that aside, because a
22 stay of your judgment, the judgment applies to all the
23 generics, and that's the relief that we are seeking as under
24 Rule 62(c), is a stay of that judgment pending appeal stays
25 it for all of them. And provided we appeal, right,

1 consistent with your order, the generics exclusivity clock
2 will -- it will run because they started it. But it's not
3 going to stop -- excuse me. It's not going to allow the
4 other generics onto the market if relief is ordered
5 consistent with a 62(c) stay motion. There won't be the
6 maneuver as it were.

7 And I will just add that, as Mr. Wallace
8 acknowledges, the other generics don't even have tentative
9 approval yet. So in some sense, the jockeying that we're
10 talking about, we were told frequently in this case that we
11 were acting precipitously and being premature because the
12 FDA hadn't done this and the FDA hadn't decided that. Well,
13 the FDA hasn't decided that the other generics even have
14 applications that should be approved yet.

15 So at some level, we're talking about the
16 hypothetical and something that can't be dealt with, but I
17 will say vis-a-vis Anchen, we absolutely intend to appeal
18 that so that the generic exclusivity clock wouldn't have
19 started running but for Mylan's decision to launch.

20 THE COURT: All right. Thank you very much.

21 And I don't know, Mr. Marsden, do you want to
22 address the bond issue, and then I will have defendants
23 respond.

24 MR. MARSDEN: Thank you, your Honor.

25 Just briefly, the bond, I think, actually goes

1 to this question of how can you protect Mylan, and there
2 is a disagreement about the amount of the bond, and we would
3 be happy to address that more fully with your Honor,
4 although we only got their opposition last evening at about
5 11:30, so we have not had a chance to fully consider that.

6 We did propose in our form of order a \$1 million
7 bond. That was not a number we picked out of thin air.
8 That's actually the number that was in the Ivax order that
9 we modeled our form of order after.

10 In fact, the drug in the Ivax case was Pulmicort
11 Respules, and the sales there were more than six times the
12 sales of the drug that's at issue here. So we think
13 actually the million dollar bond is quite reasonable, but
14 we're also prepared to address the arguments that were made
15 in the opposition that was filed last evening.

16 I will say we need some more information, I
17 think, to respond to that opposition. You'll see when you
18 review it that it's supported by a declaration from a
19 Mr. Mauro. And although we received a draft of that on
20 Friday, we were told it was highly confidential, so we
21 couldn't share it with businesspeople inside Cephalon and
22 therefore weren't really able to respond to it.

23 More importantly, the declaration, when you
24 review it, your Honor, you'll see it's quite conclusory, and
25 I'm not going to refer to the numbers because of the

1 agreement Mr. Wallace and I made before coming into by the
2 court. But you'll see, yes, there are some numbers cited,
3 but how those numbers were calculated is nowhere in the
4 declaration, and in order to respond, we need some basic
5 information, how much have they sold, at what price, what
6 their profit margins are, and then we can have some sense of
7 how they arrived at the number. Otherwise, it does not make
8 sense.

9 There's also a portion, almost a third of the
10 number they're asking for, that relates to a period after
11 the 180-day exclusivity, and we don't understand the basis
12 for that at all.

13 So the upshot of this, your Honor, is, you can
14 set the appropriate amount of bond after we've been heard on
15 what that amount of bond should be, and we think that
16 addresses whatever considerations should be given to the
17 harm that Mylan may have suffered.

18 I also wanted to briefly address the recall
19 issue that Mr. Wallace also raised.

20 It's our understanding that there is no
21 regulation requiring that recalled product be destroyed. It
22 is true that good manufacturing practices would require that
23 you be able to understand how the drug was stored, but at
24 least to the extent that this drug that has been shipped is
25 in warehouses, it should be relatively easy for Mylan to

1 reconstruct what the custody has been and how the drug has
2 been stored.

3 With respect to the other factors -- and, your
4 Honor, we don't know what their cost of goods is, but
5 generally the generic's cost of goods is quite low, so even
6 if that product had to be destroyed, we don't believe that
7 damages would be large.

8 With respect to the customer relations and other
9 issues, I think that goes to the point that Mr. Singer
10 raised, which is this is a self-inflicted wound, to a large
11 degree.

12 The only other issue I will raise for now on the
13 form of the order is we had included a ban on manufacturing.
14 I told Mr. Wallace when I came into by the court today that
15 we agree that that can come out of the proposed order, but
16 we otherwise believe that the order should be entered as we
17 provided it to the other side, and we're prepared to hand up
18 that form of order to your Honor this morning.

19 THE COURT: All right. Thank you very much.

20 MR. MARSDEN: Thank you.

21 THE COURT: Mr. Wallace?

22 MR. WALLACE: I apologize for my laryngitis.

23 And that's the reason I'm trying to be more of a good
24 listener today than a talker.

25 Several points. I will be very brief, your

1 Honor. It is absolutely incorrect that all generic
2 potential competitors are covered by your Honor's judgment,
3 because Impax is out of the case. They have a deal with
4 Impax. I've never seen it. I don't know what it says, but
5 they're not going to be governed by whatever your Honor does
6 with your judgment. All right? So that's another potential
7 triggering possibility.

8 As far as the amount of the bond is concerned, I
9 will take plaintiffs at their word. Gross sales are now 170
10 million. I will take Mr. Singer at his word. Generics will
11 capture 90 percent of the market. That gives the generics
12 \$153 million in sales first year.

13 I will take Mr. Marsden's word, the generic
14 costs are quite low. So we're talking about, by their
15 calculations, Mylan in a year should sell \$75 million in
16 product with costs quite, quite low. A million dollar bond
17 is not even in the same universe, your Honor.

18 The recall -- it's very easy for Mr. Marsden to
19 say, well, we can ask people where they kept product in the
20 warehouse, but as your Honor knows, sometimes evil people
21 tamper with drugs. You remember the Tylenol scare that
22 almost brought Johnson & Johnson to its demise.

23 Mylan has good manufacturing practices. Whether
24 it's required by the law or not, Mylan is not going to
25 gamble on its reputation. Any product that's recalled,

1 regardless of Mr. Marsden's lecture about the law, will be
2 destroyed, period. It's not negotiable.

3 I do want to just briefly mention two Federal
4 Circuit cases that I found last night, which may or may not
5 be -- and I think are not in our briefs, and I apologize.
6 We've been filing a lot of briefs, and I apologize, your
7 Honor.

8 One is the Reebok case, 32 F. 3d 1552 from
9 1994. And the other is the PGH case from the Federal
10 Circuit, 469 F. 3d at 1361 from 2007.

11 And I cite these two cases for a very important
12 proposition, and that relates to the four-part test. The
13 Federal Circuit in these two cases -- and these are cases
14 for publication. The Lily case that they keep talking about
15 is a not for publication, non-precedential case. These are
16 two cases for publication, officially reported.

17 Both cases make it quite clear that if the party
18 requesting injunctive relief cannot show probability of
19 success, that is absolutely the end of the discussion.
20 There's no weighing of the other factors. No probability of
21 success, end of discussion.

22 And as your Honor knows from our paper we filed
23 on Friday, 50/50 is a matter of law. We cited cases. 50/50
24 is a matter of law is not probability of success.

25 So thank you very much, your Honor. I realize

1 these are very complicated issues, and we appreciate your
2 tolerance of all the papers and motions and arguments.

3 THE COURT: One final question for you,
4 Mr. Wallace. In terms of this product that has been
5 destroyed, did you provide me in your papers the costs of
6 that product?

7 MR. WALLACE: It has not been destroyed.

8 THE COURT: Well, I mean, if --

9 MR. WALLACE: If?

10 THE COURT: If I were to embrace plaintiffs'
11 position and the terms of the injunction that they are
12 proposing, it seems to me as though one consideration I
13 would want to take into account in weighing that possibility
14 would be the costs of -- the costs of the recall, including
15 the costs of the product. And if you have not provided me
16 with a number --

17 MR. WALLACE: You're absolutely right, I have
18 not provided you with that number because the first versions
19 of the proposed injunction that we got until Friday
20 afternoon didn't even ask for a recall.

21 THE COURT: All right.

22 MR. WALLACE: I have asked Mylan to attempt to
23 get a declaration addressing that very point today.

24 THE COURT: All right.

25 MR. WALLACE: That we can get to your Honor. I

1 can tell you, it would be millions of dollars. I can't give
2 you a more precise number than that, but I knew you would
3 ask for me that, and that's why yesterday we requested that
4 Mylan move with that posthaste.

5 THE COURT: All right. Thank you, Mr. Wallace.

6 MR. WALLACE: Thank you very much, your Honor.

7 THE COURT: A final -- oh, yes, sir. Anyone
8 else? Yes. I'm sorry. All defendants.

9 MR. MIZERK: Good morning, your Honor. Don
10 Mizerk on behalf of Anchen.

11 And I wasn't planning on speaking until I heard
12 the plaintiffs say that they thought that whatever order you
13 entered would be a stay of the other defendants as well, and
14 that was news to me. If you go back to the original
15 pleading, the TRO emergency relief request that the
16 plaintiffs made, that was an injunction, the TRO only
17 against Mylan. And subsequently we have not even seen all
18 the papers because the Mylan papers were filed under seal,
19 so we don't even know what Mylan has said in response to any
20 of this that has been going on.

21 And I assume, I think that there must just be
22 some wires being crossed on the plaintiffs' side because I
23 would have assumed that if they thought that Anchen at least
24 was going to be used, this TRO motion was directed at Anchen
25 at all, that they would have shared some of these form

1 orders perhaps with Anchen during the course of this
2 proceeding.

3 So I've never seen this order that these people
4 are talking about, the plaintiffs are talking about this
5 morning, and so I think it's the facts of how this has kind
6 of played out is that clearly the plaintiffs, you know,
7 didn't intend any of this to be applied to Anchen or anyone
8 else other than Mylan, because we never even were included
9 in any discussions, any requests, any calls.

10 There were no calls to me ever from plaintiffs'
11 counsel with respect to a TRO or any other kind of
12 injunctive relief. So that being said, I'm not even
13 prepared to really respond to the substance of any kind of
14 injunction proceeding as it would affect Anchen because I
15 don't believe that that has ever been teed up by the
16 plaintiffs.

17 To the extent, though, that -- you know, I
18 reserve my rights, but to the extent there is going to be
19 any injunction, I think, then, the amount of a bond has got
20 to be substantial. And, frankly, you know, the numbers that
21 plaintiffs are throwing around, I'm having a hard time
22 seeing what the hardship is.

23 Cephalon was purchased for \$6.8 billion by
24 Teva, which is Barr. Maybe that's why Barr is not here
25 today. And the notion -- I don't know what the numbers that

1 Mylan is asking for, but certainly, you know, they have
2 probably 150 million in spare change sitting around
3 somewhere they can use to bond some kind of judgment in this
4 case.

5 So that being said, unless your Honor has any
6 questions for Anchen, but it's our position that this does
7 not affect us at all.

8 THE COURT: All right. I guess I will have a
9 question at the very end of the proceeding, and that is --
10 and I don't know whether this is an opportune time for you
11 all to get together and make sure you're all at least on the
12 same page with respect to what the outside effect of an
13 injunction might be as requested by plaintiffs, and at least
14 for you all to share some fundamental information, so if
15 anyone wants to file supplemental papers on an expedited
16 basis, you know what you're dealing with.

17 So I might ask you to have an informal
18 discussion before you all leave town.

19 MR. MIZERK: Your Honor, certainly, just on one
20 point, as far as the Anchen regulatory position at this
21 point, Mr. Singer I think mentioned that they were going to
22 appeal the Anchen case, and I think they said if they had
23 done that, then that would not terminate the stay in the
24 case. It would be a regulatory -- significant regulatory
25 event.

1 Well, your judgment in our case, irrespective of
2 whether they appeal it or not, from the FDA's perspective,
3 that terminated the 30-month stay. So the FDA has agreed to
4 give Anchen final approval and any kind of -- there's really
5 nothing else that really is pending or any other effect at
6 this point in time that the judgment has.

7 Had Mylan not launched perhaps, then there would
8 have been an additional regulatory significance to the
9 decision when it either became non-appealable, you know. So
10 if the plaintiffs didn't appeal that judgment, then it would
11 have an additional regulatory significance of perhaps
12 triggering. But now that's moot because Mylan actually has
13 launched. And so the trigger has been pulled and you
14 can't -- there's no resetting, and there's nothing, so it's
15 just a -- if the intent of appealing our judgment is simply
16 to prevent us from being a trigger, well, that's an
17 unnecessary action because the trigger has been pulled and
18 you don't need to pull it twice. Okay?

19 THE COURT: All right.

20 MR. MIZERK: Thank you, your Honor.

21 THE COURT: Anyone else from defendants'
22 perspective? I guess Barr's position maybe has changed. I
23 don't know.

24 MR. SINGER: Just very briefly, your Honor, with
25 respect to Impax, the parties have settled, but part of that

1 settlement is that if there is no generic on the market,
2 then Impax won't be on the market. And I believe there's a
3 redacted version that was actually filed with the SEC that
4 defendants are aware of that explains that, and we're happy
5 to provide that to the Court as well. So they're not going
6 to be somehow swooping in and taking the market.

7 On the actual -- just with respect to Anchen, we
8 didn't make a TRO against them because they don't have
9 tentative approval, so there's nothing to enjoin. They
10 don't have final approval, but they don't even have
11 tentative approval. As far as we know, they've provided us
12 no information that they've taken any further steps in the
13 FDA process since that hearing we had -- I think it may have
14 been a year ago right around today -- about their ANDA and
15 failure to pursue it.

16 So, again, that's with respect to Anchen. And I
17 wasn't saying that your decision had regulatory import. I
18 was just trying to explain, as Mr. Mizerk acknowledged, that
19 Mylan's decision to launch has sort of accelerated this
20 whole process, and if they had not done that, then our
21 appeal, which has been pending Anchen's decision, would have
22 prevented us from being here today.

23 And then, finally, with respect to the legal
24 standard at issue, I think Mr. Wallace misunderstands sort
25 of the underpinnings of the Court's order. And as you --

1 I'm sure you remember, your Honor, you've been through this
2 before in the Union Carbide decision. The Rule 62(c)
3 standard of the stay of judgment, which is the alternative
4 relief we moved for, we moved both to amend the Court's
5 order under 59(e) as well as for a stay under 62(c), and the
6 whole point of 62(c) is to weigh the factors.

7 The Court's order does not say that there's a
8 50/50 chance. It says that plaintiffs, it says likely as
9 not, and the Court can interpret your own language the way
10 you wish. I will simply say the Court found that the
11 likelihood of success prong weighed in favor of plaintiffs.
12 And even if it didn't, under Rule 62(c), the Court may take
13 all four factors into place, as the Court did in the Union
14 Carbide case, and weigh the balancing versus the likelihood
15 of success.

16 THE COURT: One final question.

17 MR. SINGER: Sure.

18 THE COURT: I believe Mr. Marsden mentioned a
19 party name, a case in connection with a one million bond
20 being appropriate. I'm not sure -- and I have not read the
21 papers that came in this morning. I'm not sure what that
22 was referencing, and it might be helpful to me --

23 MR. SINGER: I will let him speak.

24 THE COURT: Thank you very much.

25 MR. MARSDEN: Your Honor, it is the AstraZeneca

1 versus Ivax matter, your Honor. We have all of the papers
2 from that case because some of them were filed under seal,
3 but I believe we had we attached to one of our submissions
4 what we thought were the relevant papers, including the
5 temporary restraining order on which we modeled our proposed
6 temporary restraining order. So you should have those as
7 exhibits --

8 THE COURT: Okay.

9 MR. MARSDEN: -- to one of the briefs that we
10 filed last week.

11 THE COURT: All right. All right. As I said to
12 counsel, I don't know whether it would be helpful, since
13 you're all in the same room, to have further discussions
14 just to make sure everyone understands where they are in the
15 process.

16 Is it the case that I should give you another
17 24 hours to get me whatever else you might in connection
18 with this, or is there really no reason to wait and have me
19 go ahead and get this decision out?

20 MR. WALLACE: Your Honor, I do owe you a
21 declaration on the burdens and costs and consequences of a
22 recall. I'm hoping to get that to you today, but perhaps in
23 an abundance of caution, if we could keep the record open
24 for 24 hours.

25 THE COURT: All right. With the status quo

1 being the status quo until that time?

2 MR. WALLACE: My representation that we will not
3 ship --

4 THE COURT: All right.

5 MR. WALLACE: -- will continue.

6 THE COURT: All right. I will leave the record
7 open for 24 hours.

8 Mr. Marsden?

9 MR. MARSDEN: Your Honor, I guess our view on
10 that is it would be appropriate for you to enter formally
11 the TRO with the bond that we proposed and with the
12 understanding that we could revisit the amount of that bond
13 once we've received the additional information from
14 defendants and have had an opportunity to respond to it.

15 MR. WALLACE: Your Honor, there's certainly no
16 necessity for that. Mylan is a publicly traded corporation.
17 There are all sorts of repercussions that flow from entry of
18 injunctive relief, and I don't see why we can't let the
19 record stay open for 24 hours, let your Honor consider
20 everything that has been said today, everything that is
21 going to be filed in 24 hours, and proceed in an orderly
22 fashion. We're not shipping product.

23 THE COURT: All right.

24 MR. MIZERK: Your Honor --

25 THE COURT: Yes?

1 MR. MIZERK: -- the other Mr. Singer had
2 mentioned, that they're not asking for a TRO against Anchen
3 because they don't think they need one, so I think that
4 clarifies the position, and we don't see that this motion
5 about a TRO has any impact on Anchen.

6 THE COURT: Although the alternate was a stay of
7 judgment. I have to go back and assess. I mean, that's the
8 problem when you are trying to move things forward, is that
9 nuances sometimes get past us.

10 So you might want to have a discussion or at
11 least clarify what their position is.

12 MR. MIZERK: Well, I think there's another
13 motion for a stay of judgment that if we would respond to, I
14 need the papers in order to respond to that so I can see
15 what has been said heretofore, which we have not been able
16 to see.

17 THE COURT: All right.

18 MR. SINGER: Your Honor, I believe they've been
19 served with papers.

20 MR. MIZERK: We got some paper. Well, is this
21 the Rule 59 motion that we're talking about?

22 MR. SINGER: Yes. Rule 59 motion, which I
23 believe is publicly available and was served by ECF on
24 Mr. Mizerk on Thursday.

25 MR. MIZERK: The Rule 59 motion -- so the

1 briefing, it's not an emergency motion. It has not even
2 been -- I don't think anyone has responded to the motion for
3 a stay. I thought it was a Rule 59 motion which stays the
4 appeal, by the way. I mean, no one can file a notice of
5 appeal with a Rule 59 motion having been filed.

6 So the whole thing has just been, you know,
7 bolloxed up by some crazy motion practice, and that I think
8 was completely unnecessary. If that motion is the motion we
9 need to respond to, then we'll respond to that one. But,
10 again, I don't know that that motion, my quick reading of it
11 that landed over the weekend --

12 THE COURT: I guess I do need to work that out
13 and make sure I know what I'm addressing and make sure that
14 if I address the motion for an injunction, that the other
15 motions at that point, I don't think the Federal Circuit
16 will accept an appeal or certainly an expedited appeal if I
17 still have matters pending before me. So I think we really
18 do have to go forward on some consistent basis.

19 So would you all think about that and write a
20 letter clarifying for me ideally how we get this cleanly up
21 to the Federal Circuit so we can get their words of wisdom
22 as quickly as possible?

23 MR. SINGER: Yes, your Honor. We will do that.

24 THE COURT: All right. Counsel, thank you for
25 your patience and for educating me about this.

1 MR. MARSDEN: Your Honor, may I speak to one
2 last issue?

3 THE COURT: Yes.

4 MR. MARSDEN: I apologize. But on the timing
5 issue, although it is true that Mylan has represented to us
6 as of Friday afternoon that they are no longer selling or
7 shipping, the product that is out there is being sold in
8 pharmacies, and part of the relief that we had requested is
9 that a letter be sent by Mylan to those to whom they have
10 sold, basically informing them of the Court's order and
11 ensuring that those sales downstream are also stopped.

12 THE COURT: All right. Well, I will work as
13 quickly as I can, but I do want to have the information I
14 need to make one decision, that no motions for
15 reconsideration, you just ship it on down to Washington and
16 let them take a look at it.

17 All right. Thank you very much, counsel.

18 (Counsel respond, "Thank you, your Honor.")

19 (Court recessed at 10:03 a.m.)

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